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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,552	06/12/2000	JAY A. BERZOFSKY	15280-368200	8488

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EXAMINER	
STUCKER, JEFFREY J	
ART UNIT	**PAPER NUMBER**
1648	19

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	Examiner	Group Art Unit	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 2/6/03.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1, 3-14, 17-65 & 67-70 is/are pending in the application.

Of the above claim(s) 17-20, 23, 24, 28-41, 44, 45 & 70 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3-14, 21, 22, 25-27, 42, 43, & 46-69 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

This Office Action is in response to the amendment filed 2/6/03.

New claim 70 is drawn to an invention that is independent or distinct from the invention originally claimed, specifically, producing neutralizing antibodies, and is considered to be a different inventive concept than inducing mucosal CTL responses because the route of induction are not the same and different issues need to be considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 70 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP §821.03.

Applicant's arguments concerning the alleged inappropriateness of the restriction requirement are noted but are mute as the reasons for restriction have already been discussed in the restriction and again in the previous office action where the restriction was made final.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This application contains claims 17-20, 23, 24, 28-41, 44, 45 and 70 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). Applicant's assurance that a copy of the PCT application has been filed has been noted but the abstract has not been added to the instant file. The assurance that a copy was filed with the response is noted but no such paper is in evidence. An abstract on a separate sheet is required. Should this application be passed to issue, the printer will not go looking for a PCT application to find an abstract.

The rejection of claims 49 and 55 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

The rejection of claims 1-14, 21, 22, 25-27, 42, and 43 under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility is maintained.

Applicant argues that the treatment of, or protection from, HIV from even a single isolate of HIV can have utility. This is not convincing as applicant has not demonstrated protection from HIV of any isolate. Applicant asserts that the specification provides guidance such that the artisan can expand the CTL response to additional isolates of HIV-1 by the administration of other chimeric peptides with specific subregions and that the administration of particular compositions induced antigen specific CTL responses and induced a CTL response that killed or prevented the proliferation of recombinant vaccinia virus. As noted above, the specification provides no evidence of reducing, inhibiting, or killing HIV-1. There is evidence of an antigen specific CTL response but this is not evidence of specific, credible utility for the claimed invention.

Applicant posits that the cell to cell transmission of HIV provides evidence that the claimed methods are supported by a credible or well established utility because this type of transmission does not allegedly effect the ability of the methods of the present invention to induce the response claimed and would expect

the induction of an antigenic specific CTL response to be particularly useful in eliminating infected cells. This may be true, but, again, the specification does not support the reducing, inhibiting, or killing of free HIV-1 or infected cells *in vivo*.

Applicant does not believe that the examiner provided any particular reasons or evidence as to why the existence of latent forms of HIV would indicate that the claimed methods induce an antigen specific systemic and rectal mucosal CTL response is not supported by a credible or well established utility and that the methods of the invention are useful because the methods induce an antigen specific CTL response in the rectal mucosa and that the killing of or reduction in the proliferation of HIV in the rectal mucosa is important in the treatment of HIV infection. This is not convincing because the virus can linger in immunoprivileged sites and can remain quiescent thereby not being visible to the immune system and would not be affected by any CTL activity and therefore the invention would not be effective at reducing, inhibiting, or killing HIV-1. Because these viral reservoirs are unavailable to the immune system, the virus would not be killed, even if the invention could induce a CTL response that is effective for reducing, inhibiting, or killing HIV-1.

Applicant further argues that an induction of a CTL and immune response in the rectal mucosa to assist in the treatment of HIV

infection and that the methods of the invention provide for the first time evidence of a reduction in the proliferation of killing against mucosal viral challenge mediated by cytotoxic T cells in the rectal mucosa and that the induction of such a response can inhibit proliferation or kill virus which is known to be critical to any treatment for HIV infection. This is not persuasive because the specification does not provide evidence that the CTL response induced by the method of the instant invention reduce or kill HIV in the rectal mucosa or systemically. Further, the elected peptide of the claimed method uses a specific sequence and, given the variation in HIV, there is no evidence that it is able to reduce, inhibit, or kill HIV-1 of the immunogen strain, let alone different strains.

Applicant's point concerning the immunosuppression caused by HIV peptides is convincing to the extent that it applies to the elected sequence which can apparently induce CTL responses. This is not construed to be an assumption that the CTL response could in deed reduce, inhibit, or kill HIV-1.

Applicant submits a journal article by Belyakov et al. as evidence of either a credible asserted utility or a well established utility. This is not persuasive because the reference teaches peptides that are different from the instantly claimed peptide and, thus, the results do not necessarily correlate with

the claimed invention. The reference discloses testing with SHIV in monkeys which is not the same as HIV in humans. Refer to page 609 under "Animal Models" of Lee which teaches that "[h]owever, there is no convincing basis to conclude that protection observed in any of the animal models is suitable to predict vaccine efficacy in humans." Further, Belyakov et al. teach a specific adjuvant that is not claimed and may well play a critical role in the resulting immune response.

Researchers from all over the world have spent the last 20 or so years researching treatments and vaccines for HIV infection. Thus far, the effort has not come to fruition with many promising treatments failing to live up to early expectations. Therefore, the claimed invention is not supported by either a credible asserted utility or a well established utility.

The rejection of claims 1-14, 21, 22, 25-27, 42, and 43 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicant's arguments have not been persuasive for the reasons given above.

The rejection of claims 46-48, and 59 under 35 U.S.C. § 102(b) as being anticipated by Ahlers et al. (The J. of Imm., IDS ref. AH) is maintained.

Applicant argues that Ahlers et al. does not anticipated the amended claims because Ahlers et al. does not offer guidance as how the composition would be formulated for the mode of administration to induce a CTL response nor does the reference speculate on the tissue specificity of the CTL response and that allegedly prior to the present invention little was known about the induction of a CTL response in the rectal mucosa with a nonliving vaccine. This is not convincing because the claimed invention is a composition comprising the same peptide as the prior art. The prior art composition is in a form suitable for rectal administration. If one were to use the composition for mucosal administration, the resulting immune response is an inherent characteristic of the composition. Therefore, the instantly claimed invention is anticipated by Ahlers et al.

The rejection of claims 46-65 and 67-69 are rejected under 35 U.S.C. § 103(a) as obvious over Ahlers et al. in view of the admissions of the specification is withdrawn in view of applicant's arguments.

No claims are allowed.

THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeffrey Stucker

JEFFREY STUCKER
PRIMARY EXAMINER